Application No. Applicant(s) 10/059,895 GILLIS ET AL. Notice of Allowability Examiner Art Unit Manuel Mendez 3763 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. 1. This communication is responsive to <u>amendment dated 08/16/2004</u>. 2. The allowed claim(s) is/are 34-52. 3. The drawings filed on 18 March 2002 are accepted by the Examiner. 4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some* c) None of the: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. 6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date _ (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application (PTO-152) 2. Notice of Draftperson's Patent Drawing Review (PTO-948) 6. Interview Summary (PTO-413),

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of Biological Material

3. Information Disclosure Statements (PTO-1449 or PTO/SB/08).

4. Examiner's Comment Regarding Requirement for Deposit

Paper No./Mail Date 01/28/2002

Paper No./Mail Date

9. Other

7. X Examiner's Amendment/Comment

8.

Examiner's Statement of Reasons for Allowance

Art Unit: 3763

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In view of the patentability of the pending claims, the examiner of record hereby withdraws the "Restriction/Election of Species Requirement" presented on 07/13/2004.

Accordingly, claims 34-52 are allowable over the prior art of record.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The prior art of record does not disclose or suggest, *inter alia*, the steps of implanting a composite catheter into a subject, the composite catheter comprising an outer member comprising a proximal end, a distal end, and an outer member body defining an outer member lumen; and an inner member comprising a proximal end, a distal end, and an inner member body defining an inner member lumen, wherein the inner is interposed within the outer member lumen so as to define an interstitial space between the inner member and the outer member; wherein the inner member body comprises a substantially impermeable material, and wherein the inner member lumen defines a drug delivery conduit suitable for delivery of a drug from the inner member proximal end to the inner member distal end, wherein the implanting provides a drug delivery pathway from a proximal end of the catheter, through the inner member lumen to a distal end of

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the catheter, and out a delivery outlet positioned at a treatment site in a subject; and introducing a drug into the inner lumen of the catheter wherein the drug is delivered to the treatment site in the subject.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

> Manuel Mendez) Primary Examiner Art Unit 3763

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